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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,030	03/01/2004	Joel R. Studin	SDF 04-1	7162

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,030

Applicant(s)

STUDIN, JOEL R.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in reference to the applicant's reply filed 3/2/06.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kousai et al (4874372). Kousai teaches a breast implant injector device having a hollow cylinder (11) having opposed open filling and injection ends (Fig 8-10) with the injection end having a narrower diameter than the opposed filing end (Fig 8-10), the cylinder having an elongated slot (Fig 11, 14) extending from the injection end to the opposed filling end (Fig 11, 14), an elongated plunger (2, 3) capable of passing through the interior of the cylinder (11; Fig 8-10) and having a flattened end, being defined as the proximal end of syringe (2), to provide sufficient surface area to push an implant, being the contents of syringe (2) through the cylinder, and an outwards abutment surface, being defined as the slope from the narrow diameter portion of (11) to the larger diameter portion on the filing end (Fig 8) that is adjacent to the filling end surface (Fig 8) to provide a surface onto which increased finger pressure can be applied.
4. Claims 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ash et al (4408902). Ash et al teaches a combination of a breast implant injector device (10)

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and an unfilled breast implant, defined as the portion of (22) located in the musculature side (28) below the dacron cuff (24; Fig 6) and shown to be positioned in the interior of a hollow cylinder (10) during injection (Fig 5), containing a fill tube (22) extending therefrom, the combination including a hollow cylinder (10) having opposed open ends (Fig 5), including a filling end and an injection end (Fig 5), the breast implant lying (Fig 5) within the hollow cylinder with the fill tube (22) extending from the interior of the said hollow cylinder through an elongated slot that extends from the injection end to the opposed filling end (12; Fig 5). The Examiner takes the position that an unfilled breast implant as recited can be any unfilled implant that is disposed within a breast.

Therefore, the portion of (22) located on the musculature side (28) below the dacron cuff (24; Fig 6) can be considered by one of ordinary skill in the art at the time the invention was made as being an unfilled breast implant because it is capable of being implanted in a breast and it is capable of being filled with fluid by injecting fluid into fill tube (22). The Examiner suggests that the Applicant further define the breast implant to include limitations recited in the specification such as being a fixed or changeable-volume sac-like silicone rubber structure in order to distinguish over prior art. It is noted, that it appears that the features upon which Applicant relies (i.e., a specific structure and size of an unfilled breast implant) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al in view of Kousai et al. Ash et al discloses the invention substantially as claimed except for the injection end being of a narrower diameter than the filling end. Kousai et al teaches that it is known to have the injection end being of a narrow diameter than the filling end for the purpose of providing tighter contact with the inner cannula (col 4, ln 30-34) for a smaller incision. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hollow cylinder as taught by Ash et al with the injection end being of a narrow diameter than the filling end as taught by Kousai et al for the purpose of providing tighter contact with the inner cannula (col 4, ln 30-34) for a smaller incision.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al in view of Kousai et al. Ash et al discloses the invention substantially as claimed except for an outward abutment surface adjacent to the filing end. Kousai et al teaches that it is known to have an outward abutment surface (see discussion above) for the purpose of providing tighter contact with the inner cannula (col 4, ln 30-34) for a smaller incision. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hollow cylinder as taught by Ash et al with the

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outward abutment surface formed by the transition between the narrow diameter injection end to the larger diameter filing end as taught by Kousai et al for the purpose of providing tighter contact with the inner cannula (col 4, ln 30-34) for a smaller incision.

8. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al in view of Kousai et al. Ash et al discloses the invention substantially as claimed except for an elongated plunger capable of passing through the interior of the cylinder and having a flattened end. Kousai et al teaches that it is known to have an elongated plunger (2, 3) capable of passing through the interior of the cylinder (11; Fig 8-10) and having a flattened end, being defined as the proximal end of syringe (2), for the purpose of providing sufficient surface area to push an implant, being the contents of syringe (2), through the cylinder. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection device as taught by Ash et al with the plunger with a flattened end as taught by Kousai et al for the purpose of providing sufficient surface area to push an implant through the hollow cylinder.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al in view of Roser (6102896). Ash et al discloses the invention substantially as claimed except for enclosing the breast implant and cylinder in a sanitary package. Roser teaches that it is known to have a sterile package enclosing a medical injection device for the purpose of controlling the spread of disease and limiting the patient from being contaminated (background). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the breast implant device as taught

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by Ash et al with the sterile packaging as taught by Roser for the purpose of controlling the spread of disease and limiting the patient from being contaminated.

Allowable Subject Matter

10. Claim 13 is allowed.

11. No prior art of record could be found to teach or suggest the subject matter of independent claim 13. The subject matter not found was structure recited in the method comprising an injector device having a hollow cylinder with an elongated slot extending from the injection end towards the filling end and an unfilled breast implant that fits within the hollow cylinder with a fill tube extending from the interior of the hollow cylinder through the elongated slot in combination with the other elements, or steps, in the claim.

Response to Arguments

12. Applicant's arguments with respect to claims 6-12 have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments filed 3/2/2006 regarding claims 1 and 3-5 being rejected under 35 U.S.C. 102(b) as being anticipated by Kousai et al (4874372) have been fully considered but they are not persuasive.

14. The Applicant argues that the presence of "breast implant" in the preamble not only gives meaning to the claimed elements, but is essential to pointing out that the device is to be used for breast implants. The preamble clearly requires that the claimed element, "a hollow cylinder", be dimensioned and configured to receive a breast implant. (REMARKS, pg 2, paragraph 2-3).

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15. In response to applicant's arguments, the recitation "breast implant injector device" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The argument that the hollow cylinder of Kousai cannot receive a breast implant is non-persuasive because breast implants are known to vary in size (ie – A cup to C cup and a breast implant can also be any implant that resides in the breast) and Kousai is known to have a diameter dimensioned for implantation (ie – 12G to 16G, or .729 in - .663 in, see col 4, ln 33). Thus, Kousai can receive a breast implant and is capable of functioning as a breast implant introducer as claimed. It is noted, that it appears that the features upon which applicant relies (i.e., a specific structure and size of a breast implant) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

16.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

KEVIN SIRMONS
PRIMARY EXAMINER

